

Notice of Allowability

Application No.

10/057,776

Applicant(s)

BERLIN, KURT

Examiner

Art Unit

Young J. Kim

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the Amendment received on May 25, 2006.
2. ☒ The allowed claim(s) is/are 1-6 and 8-14.
3. ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some* c) ☐ None of the:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
- (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying Indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☒ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date 5/25/06
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☐ Interview Summary (PTO-413),
Paper No./Mail Date _____.
7. ☐ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

Young J. Kim
Primary Examiner
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8-3-06

DETAILED ACTION

Claim Rejections - 35 USC § 112

The rejection of claim 2 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter, made in the Office Action mailed on November 23, 2005 is withdrawn in view of the Amendment received on May 25, 2006.

Claim Rejections - 35 USC § 103

The rejection of claims 1-3, 6-10, 12, and 13 under 35 U.S.C. 103(a) as being unpatentable over Gonzalgo et al. (WO 98/56952, published December 17, 1998) in view of Yurov et al. (Human Genetics, 1996, vol. 97, pages 390-398) and in light of Davis et al. (U.S. Patent No. 6,046,002, issued April 4, 2000, filed January 5, 1998), made in the Office Action mailed on November 23, 2005 is withdrawn in view of the Amendment received on May 25, 2006.

The rejection of claims 4 and 5 under 35 U.S.C. 103(a) as being unpatentable over Gonzalgo et al. (WO 98/56952, published December 17, 1998) in view of Yurov et al. (Human Genetics, 1996, vol. 97, pages 390-398) and in light of Davis et al. (U.S. Patent No. 6,046,002, issued April 4, 2000, filed January 5, 1998), as applied to claims 1-3, 6-10, 12, and 13 above, and further in view of Apffel et al. (U.S. Patent No. 6,379,889 B1, issued April 30, 2002, filed November 4, 1999) and Roche et al. (Biotechnology Progress, 1997, vol. 13, pages 659-668), made in the Office Action mailed on November 23, 2005 is withdrawn in view of the Amendment received on May 25, 2006.

The rejection of claim 11 under 35 U.S.C. 103(a) as being unpatentable over Gonzalgo et al. (WO 98/56952, published December 17, 1998) in view of Yurov et al. (Human Genetics, 1996, vol. 97, pages 390-398) and in light of Davis et al. (U.S. Patent No. 6,046,002, issued April 4, 2000, filed January 5, 1998), as applied to claim 1 above, and further in view of Wang et al. (Science, May 1998,

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vol. 280, pages 1077-1082), made in the Office Action mailed on November 23, 2005 is withdrawn in view of the Amendment received on May 25, 2006.

The rejection of claim 14 under 35 U.S.C. 103(a) as being unpatentable over Gonzalgo et al. (WO 98/56952, published December 17, 1998) in view of Yurov et al. (Human Genetics, 1996, vol. 97, pages 390-398) and in light of Davis et al. (U.S. Patent No. 6,046,002, issued April 4, 2000, filed January 5, 1998), made in the Office Action mailed on November 23, 2005 is withdrawn in view of the arguments presented in the Amendment received on May 25, 2006 and in careful reconsideration of the application.

Double Patenting

The provisional rejection of claims 1-13 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-29 of copending Application No. 10/220,090 (herein the '090 application), made in the Office Action mailed on November 23, 2005 is withdrawn.

The rejection of claims 1-13 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-26 of copending Application No. 10/220,896 (herein the '896 application), made in the Office Action mailed on November 23, 2005 is withdrawn.

The withdrawal of the above provisional obviousness-type double patenting rejections is based on the instructions provided for by MPEP 804(I)(B)(1):

"If "provisional" ODP rejections in two applications are the only rejections remaining in those applications, the examiner should withdraw the ODP rejection in the earlier filed application thereby permitting that application to issue without need of a terminal disclaimer."

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The present application is the earlier filed application of the above-recorded applications and thus, the provisional ODP rejections are withdrawn accordingly.

Reasons for Allowance

The following is an examiner's statement of reasons for allowance:

While the prior art discloses a method of detecting the methylation pattern of a nucleic acid, wherein the method comprises the steps of: a) bisulfite treatment; b) amplification with unlabeled nucleotides; followed by the sequencing of the amplified product with labeled nucleotides (i.e., Herman et al. (U.S. Patent No. 5,786,146)), or by a single-nucleotide extension of the amplified products (which are unlabeled; i.e., SNuPe reaction; Gonzalgo, of record), wherein the single-nucleotide is labeled, the prior art **fails to provide a sufficient motivation** for one of ordinary skill in the art to amplify the bisulfite-treated DNA with fluorescently labeled nucleotides, dCTP or dGTP, and quantitating the fluorescence measurement of said amplified product which comprises said fluorescently labeled nucleotides. The prior art does not motivate why the bisulfite-treated DNA should be labeled during its amplification process, as the actual identification of methylation status in all of prior art methods first amplify the DNA with unlabeled nucleic acid, followed by subsequent steps which further manipulate the amplified DNA with labeled nucleotides (either by SNuPe or Sequencing reaction).

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

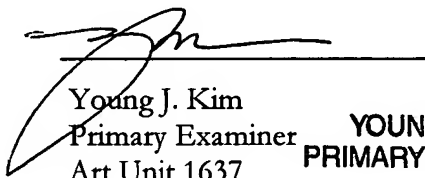
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Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Young J. Kim whose telephone number is (571) 272-0785. The Examiner is on flex-time schedule and can best be reached from 8:30 a.m. to 4:30 p.m (M-W and F). The Examiner can also be reached via e-mail to Young.Kim@uspto.gov. However, the office cannot guarantee security through the e-mail system nor should official papers be transmitted through this route.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Dr. Gary Benzion, can be reached at (571) 272-0782.

Papers related to this application may be submitted to Art Unit 1637 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If applicant does submit a paper by FAX, the original copy should be retained by applicant or applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office. All official documents must be sent to the Official Tech Center Fax number: (571) 273-8300. For Unofficial documents, faxes can be sent directly to the Examiner at (571) 273-0785. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (571) 272-1600.


Young J. Kim
Primary Examiner
Art Unit 1637
8/3/2006
**YOUNG J. KIM
PRIMARY EXAMINER**

YJK